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Attachment D

510(k) Summary of Safety and Effectiveness

Submitter Information (21CFR 807.92 (a)(1))

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Name of Device and Classification (21CFR 870.92 (a)(2))

Name: FACS Loader™ accessory device

Classification: Accessory to 21 CFR 864.5220, Class II
Automated Differential Cell Counter

Predicate Device (21 CFR 807.92 (a)(3))

The FACS Loader is an accessory to the Becton Dickinson family of flow cytometers. It is substantially equivalent to the manual method of introducing sample tubes to the cytometer in previously cleared applications for immunophenotyping and reticulocyte enumeration. These include Simultest™ reagent systems (such as K913192 and K923790) and the Retie-COUNT™ system (most recently cleared as K880636).

Description of the Device (21 CFR 807.92(a)(4))

The Becton Dickinson FACS Loader is a computer-controlled sample handling device for resuspending and introducing immunophenotype and reticulocyte samples to the flow cytometer. The loader is designed for use with the BDIS systems for immunophenotyping and reticulocyte enumeration which consist of a flow cytometer, reagents and application software for lymphocyte and reticulocyte identification, and a computer, as well as software for cytometer set-up and sample acquisition and analysis. The loader is supplied with WorklistManager and LoaderManager software. The WorklistManager communicates with other acquisition and analysis software to specify assays, reagent panels and data storage of sample information. The

LoaderManager software provides sample acquisition status as well as loader maintenance and diagnostic information.

To use the FACS Loader, a technician prepares each blood sample according to reagent package insert instructions using 12 x 75 mm test tubes. Up m 40 prepared tubes are then placed into a loader carousel coded with an optically readable identity number. As the carousel automatically rotates for sample introduction to the flow cytometer, cycloidal mixing occurs to keep samples resuspended while awaiting analysis. An initial mix of 10 seconds occurs when the carousel is first placed on the loader and is followed by shorter mixes at predetermined intervals until all samples on the carousel have been acquired. Once a tube is moved into position for loading, a tube lifter mechanism pushes it from below to the sample intake probe. When the sample tube is engaged to the cytometer, sample acquisition and data analysis occurs utilizing BDIS application software.

Intended Use (21 CFR 807.92(a)(5))

The FACS Loader is intended for use as an accessory to the Becton Dickinson family of flow cytometers for the purpose of handling prepared blood samples for introduction to the cytometer. It is used in applications for immunophenotyping and reticulocyte enumeration.

Comparison to the Predicate (21 CFR 807.92 (a)(5)(6)

The loader and manual application procedures are both intended to thoroughly mix and introduce prepared blood samples to the flow cytometer to acquire data files for analysis using appropriate software. The automatic and manual methods differ in that the prepared sample is periodicall$_y$ resuspended with the loader mixin$_g$ cycle. Manual methods require additional mixing if samples are not analyzed immediately after preparation. For all applications, label claims for age of sample and age of stain prior to analysis remain the same for both the manual and loader methods.

Additionally, the loader software allows a worklist for application control and data file storage, The software also includes loader maintenance and diagnostic capabilities.

Performance Data (2 I CFR 807.92(b)(2)

The product performance was established b$_y$ testing at Becton Dickinson Immunocytometry Systems laboratories in San Jose, California usin$_g$ the FACSort™ flow cytometer, HP 340 or Macintosh computer, and application software Retie-COUNT and SimulSET™. For accuracy of reticulocyte enumeration and immunophenotyping, the mean difference between the predicate and loader method fell within the acceptance criteria of ±0. j%. Loader precision also met the acceptance criteria of ±0.5% for differences detected with 950/o confidence; performance for immunophenoty ping was within an acceptable 30/o or a relative 10% of the measurements for all 4 response variables. The followin$_g$ studies were performed:

Reticulocyte Enumeration

- Accuracy of reticulocyte percent enumeration was determined by comparing results of samples from the same specimen tested using the FACS Loader and the predicate method. Lysed whole blood samples from 11 normal and 19 abnormal donors were analyzed using both methods and Retie-COUNT application reagent and software. Accuracy data demonstrated the FACS Loader's equivalence to the manual method.

- Within-specimen reproducibility (precision) tests for percent reticulocytes were performed on samples from 11 normal and 19 abnormal donors. The study tested samples in three representative carousel positions, each with 3 aliquots from the same specimen. Results showed acceptable within-sample reproducibility for the tested carousel positions.

Immunophenotyping

- The accuracy of lymphocyte percent enumeration was verified by comparison to the predicate method using representative reagents LeucoGATE™, control, CD3/CD4 and CD3/CD8. Lysed whole blood samples from 24 normal and 20 abnormal donors were divided to stain 7 sample panels each for the manual test compared to different positions on 3 carousels. Accuracy results demonstrated equivalence of the loader method to the predicate for response variables $CD3^+$, $CD3^+CD4^+$ and $CD3^+CD8^+$.

- Within-specimen reproducibility (precision) for 24 normal and 20 abnormal donors was evaluated by testing two carousel positions. Seven panels were stained with the representative reagents and, except for 1 manual test, divided into 2 positions on 3 carousels for comparison. Results verified within-specimen reproducibility for the 2 carousel positions for $CD3^+$, $CD3^+CD4^+$ and $CD3^+CD8^+$ values.

Performance Data–Conclusions (21 CFR 807.92 (b)(3))

The results of the performance studies demonstrate that the device is as safe and effective as the predicate, or manual method.

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7/11/95
Date